

## **HANDY SOLUTIONS HEADACHE PAIN RELIEF- acetaminophen, aspirin, caffeine tablet, film coated**

**Navajo Manufacturing Company Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Handy Solutions® Headache Pain Relief**

#### ***Drug Facts***

##### ***Active ingredients (in each tablet)***

Acetaminophen 250 mg

Aspirin (NSAID\*) 250 mg

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

##### ***Purposes***

Pain Reliever/Fever Reducer

Pain Reliever Aid

##### ***Uses***

For the temporary relief of minor aches and pains associated with

• headache • muscular aches • minor arthritis pain • back pain • common cold • toothache • menstrual cramps

Temporarily reduces fever.

##### ***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin (NSAID) may cause a severe allergic reaction which may include:

• hives • skin reddening • facial swelling • rash • asthma (wheezing) • shock • blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**Liver Warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or

others)

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for pain for more than 10 days unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you ever have had an allergic reaction to any other pain relievers/ fever reducers
- right before or after heart surgery
- if you are taking prescription drugs for gout, diabetes, or arthritis

### **Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have a history of stomach problems such as heartburn
- you have asthma

### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- under a doctor's care for any serious condition
- taking any other drug

### **When using this product**

- take with food or milk if stomach upset occurs

### **Stop use and ask a doctor if**

you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- symptoms do not improve
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms appear

### **If pregnant or breast-feeding,**

ask a health care professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

### **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### ***Directions***

- do not use more than directed
- Adults and children (12 years and older):** Take 2 tablets with water every 6 hours as needed. Do not take more than 8 tablets in 24 hours.
- Children under 12 years: Do not give to children under 12 years of age.

Other Information

- read all product information before using
- store at room temperature 59°-86°F (15°-30°C)
- avoid excessive heat and humidity • tamper evident sealed packets
- do not use any opened or torn packets

Inactive Ingredients

hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide

Questions or comments?

call 1-800-525-5097

Package Labeling:



HANDY SOLUTIONS HEADACHE PAIN RELIEF			
acetaminophen, aspirin, caffeine tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-175(NDC:47682-228)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	250 mg

ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		CAFFEINE	65 mg	
Inactive Ingredients				
Ingredient Name			Strength	
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white (white)	Score	no score	
Shape	ROUND (ROUND)	Size	11mm	
Flavor		Imprint Code	FR;9	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-175-01	1 in 1 CARTON	10/21/2016	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part343	10/21/2016	

**Labeler** - Navajo Manufacturing Company Inc. (091917799)

## Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-175)

Revised: 11/2019

Navajo Manufacturing Company Inc.